DOD CIVILIAN

INSTALLATION BIOCHEMICAL

TESTING PROGRAM

FORT RILEY, KS

SOP
2006

ARMY SUBSTANCE ABUSE PROGRAM
(ASAP)

FORT RILEY, KANSAS 66442

SOP ANNUAL REVIEW SHEET

TITLE: STANDING OPERATING PROCEDURES FOR THE DOD CIVILIAN URINALYSIS DRUG TESTING PROGRAM

AUTHORIZED BY: CARRIE JENSEN (IBTC) **DATE:** 11 OCTOBER 2006
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DEPARTMENT OF THE ARMY
OFFICE OF THE STAFF JUDGE ADVOCATE
HEADQUARTERS, 1ST INFANTRY DIVISION and FORT RILEY
FORT RILEY, KANSAS 66442

AFZN-JA-CIV 11 OCTOBER 2006

MEMORANDUM FOR Carrie Jensen, installation Biochemical Testing Coordinator (IBTC), Soldier and Family Support Center, Fort Riley, Kansas 66442

SUBJECT: DA Civilian Urinalysis Testing SOP

1. There is no legal objection to the Standard Operating Procedures for biochemical (urinalysis) testing of Department of Army civilians on Fort Riley. The procedures listed comply with Army Regulation 600-85, Department of Army Pamphlet 600-85, the Urine Specimen Collection Handbook for Federal Workplace Drug Testing Programs, and the DA Memorandum, Subject: Fiscal Year (FY06) Random Drug Testing Rates for Testing Designated Position (TDP) and Department of Transportation (DOT) Categories, 27 Sep 05.

2. Point of contact is the undersigned at 239-6221.

FOR THE STAFF JUDGE ADVOCATE:

//ORIGINAL SIGNED//
ERIC L. CARTER
Civil Law Attorney

DEPARTMENT OF THE ARMY
ARMY SUBSTANCE ABUSE PROGRAM (ASAP)
FORT RILEY, KANSAS 66442

IMNW-RLY-MWA 27 September 2006

STANDING OPERATING PROCEDURE (SOP)
ARMY SUBSTANCE ABUSE PROGRAM
INSTALLATION BIOCHEMICAL TESTING PROGRAM (IBTP)
DEPARTMENT OF ARMY CIVILIANS

1. GENERAL.

a. The Biochemical Testing Program is designed to assist the installation in determining the extent of illegal drug use on Fort Riley. Testing also determines the illegal drug use upon entry into the Army Substance Abuse Program (ASAP) rehabilitation services and is an indicator of non-involvement with illegal drugs during the rehabilitation process. Organizationally, the IBTP is a service of the installation ASAP which is under the functional control of the ASAP Director (ASAPD).

b. The Fort Riley IBTP is located on Custer Hill, Building 7264, and is responsible for collecting local urinalysis samples, packaging, and shipping them to the Forensic Toxicology Drug Testing Laboratories (FTDTL). Additionally, the IBTP maintains a database that assists civilian supervisors in identifying drug abuse trends within directorates on the installation.

2. REFERENCE. The Standard Operating Procedure (SOP) for the Installation Biochemical Testing Program (IBTP) was written in accordance with:

a. Army Regulation (AR) 600-85, dated 24 March 2006.

b. Department Of Defense (DOD) Directive 1010.1

c. Urine Specimen Collection Handbook for Federal Workplace Drug Testing Program, dated November 1, 2004.

d. AR 195-5

e. Department of Army (DA) Pamphlet600- 85.

3. PURPOSE. This SOP provides guidelines and detailed instruction on the procedures that must be followed in the collection and shipment of urinalysis specimens from Department of Army (DA) Civilians. Deviation or modification of the procedures set forth in this SOP is not

authorized without written approval of the Fort Riley ASAPD. Request for authority to deviate from, supplement or modify any procedures set forth in this SOP must be submitted in writing to the ASAP Director, Building 7264, Fort Riley, Kansas 66442.

4. OBJECTIVES.

a. Early identification of illegal drug use.

b. Deterrence of experimental and casual use.

c. Monitoring of the rehabilitation progress for those who require testing as a part of their rehabilitation plan.

d. Development of data on the prevalence of drug abuse at Fort Riley.

5. POLICY. Biochemical testing for a controlled substance is a tool for Management and the Agency physician to use for the purposes listed below:

a. To test all DA civilian employees subject to reasonable suspicion testing (i.e., when there is a reasonable suspicion of on-duty use or on-duty impairment).

b. To test DA employees in Testing Designated Positions (TDPs) subject to reasonable suspicion testing (i.e., when there is a reasonable suspicion that an employee uses illegal drugs, whether on- or off-duty).

c. To randomly test DA employees who are in TDP positions at the rate of 75% per year from the TDP pool.

d. To identify personnel for referral to counseling, treatment and rehabilitation.

e. To determine the presence of a controlled substance in an employee's urine during participation in the ASAP outpatient rehabilitation.

6. RESPONSIBILITIES.

a. The ASAP Director is responsible for:

(1) Ensuring that the procedures set forth in this SOP are followed in the collection of DA civilian specimens.

(2) Ensuring that random selection of DA civilian personnel to be tested will be done by using the Army Computer Drug Testing Program (ACDTP).

(3) Notifying DA civilian personnel of testing time and location.

(4) Coordinating testing location, time and names of personnel to be tested.

(5) Ensuring that all results on DA civilians are directed to the Medical Review Officer (MRO) within 24 hours of receipt and not released to any other individual.

(6) Ensuring that a separate Chain of Custody form and permanent Record Book are utilized for DA civilian specimens. There cannot be a mixture of DA civilian or any other testing category samples on the same form or Permanent Record Book.

(7) Maintaining sufficient supplies to conduct DA civilian drug testing.

b. The Installation Biochemical Testing Coordinator is responsible for:

(1) Setting up collection site designated by the ASAPD.

(2) Conducting testing.

(3) Ensuring Chain of Custody documentation is correct.

(4) Packaging and shipping all samples to FTDTL.

7. SUPPLIES.

a. Equipment needed for drug testing:

(1) Book, Memorandum Ruled, 14 x 8½ inches not indexed. NSN 7530-00-286-8363.

(2) Federal Drug Testing Custody and Control Form (OMB NUMBER 0930-0158).

(3) Urine Drug Screen Collection Kit.

(4) Box, Shipping - NSN 8115-01-386-2285.

(5) Bluing Agent. Available from commercial sources.

(6) Paper, Kraft Untreated, Wrapping (24 inch) - NSN 8135-00-290-3407.

(7) Tape, Gummed Kraft, 3-inch wide medium weight - NSN 8135-00-270-8717.

(8) Pouch, Mailing - NSN 6530-01-304-9745.

(9) Gloves, Patient Examining - NSN 6515-00-462-0832.

8. SET UP OF COLLECTION SITE.

a. Prior to the collection time, the collection site will be closed and will be secured for the duration of the collection procedure. The only persons authorized to enter the collection site will be the individual submitting the specimen and the collection site personnel.

b. The collection site will be inspected by the collection site personnel in the following manner:

(1) All cleaning materials, i.e., glass cleaner, cleaning powders, soap, disinfectants, etc., will be removed from the collection site.

(2) Trashcans will be emptied.

(3) Water hoses will be removed from the collection site. Any other water sources other than the sink and toilet will be shut off.

(4) If applicable liquid soap containers will be wrapped with a plastic bag and sealed with tape on the top of the container or at the base of the container where it meets the wall.

(5) The sink soap holders and counter tops will be cleaned so there is no residue left when the surface is dry.

(6) Paper towels may be left out for use. Toilet paper may be left in place for use.

(7) The toilet will be partitioned from any and all water source except for the water in the toilet bowl.

(8) A bluing agent will be placed in the toilet water after the last person flushes.

c. If the individual to be tested fails to arrive at the assigned time, the Collection Site Personnel (CSP) shall wait 30 minutes. If after this grace period of time the individual to be tested fails to arrive at the Collection Site, the CSP shall contact the ADCO.

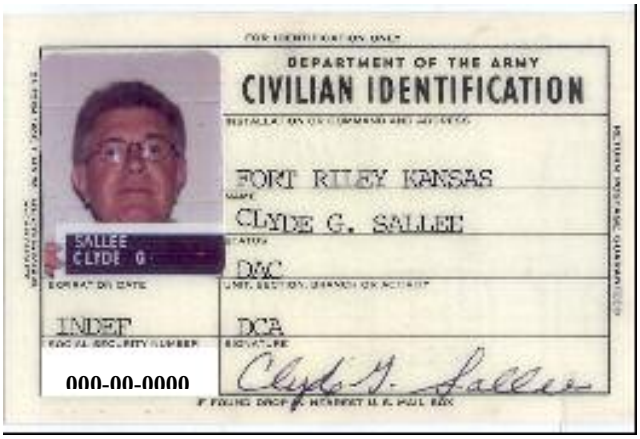
d. There will be no eating, drinking, smoking, or chewing during the actual collection procedure.

Note: The collector's work area must be located outside the rest room. However, if there is no appropriate space available outside the rest room to serve as a work area and the rest room is large enough to accommodate a work area, the work area may be located inside the rest room as long as the donor has privacy while providing a urine specimen and the collector is the same gender as the donor.

9. DONOR IDENTIFICATION:

a. The donor must provide appropriate identification to the collector upon arrival at the collection site. Acceptable forms of identification include:

(1) Photo identification (e.g., driver's license, employee badge).



(2) Identification by first level supervisor's direct sight confirmation.

b. Unacceptable forms of identification include:

(1) Identification by a co-worker;

(2) Identification by another donor;

(3) Use of a single non-photo identification card (e.g., social security card, credit card, union or other membership cards, pay vouchers, voter registration card).

10. COLLECTION PROCEDURES.

a. The following steps describe a typical urine collection procedure under the Mandatory Guidelines:

(1) The collector prepares the collection site to collect urine specimens. All collection supplies must be available, the area properly secured, water sources secured, and bluing agent placed in all toilets.

Note: If access to a water supply in the restroom cannot be controlled, the collector may tell the donor that he or she will be listening at the entrance to the restroom for any sounds associated with the donor attempting to use the available sources of water. Alternatively, the collector may enter the restroom with the donor if the collector is the same gender as the donor, but remains outside the toilet stall.

(2) The collector begins the collection without delay after the donor arrives at the collection site.

Note: Do not wait because the donor is not ready, is unable to urinate, or an authorized employer

or employee representative is delayed in arriving.

(3) The collector requests the donor to present an acceptable form of identification as described above.

Note: If the donor cannot satisfy the identification requirement, the collector may proceed with the collection if the donor can provide two items of identification bearing his or her signature. After the donor signs the certification statement, the collector should compare the donor's signature with signatures on the identification that was presented. If the signatures match, the collector lists on the "Remarks" line the two items of identification used to identify the donor and states "signature identification was confirmed." The collector then continues with the collection process. If the signature does not match the signatures on the two items of identification presented, the collector should state on the "Remarks" line that "signature identification is unconfirmed," discontinue the collection, and notify the collection site supervisor and the agency.

Note: In situations where the donor does not have either photo identification or two other appropriate items of identification that could be used to verify identity and signature, this should not be automatically considered a refusal to test. The collector should proceed with the collection. The collector should provide sufficient information on the "Remarks" line to help the MRO and the agency make a determination regarding the validity of the specimen and the collection process.

Note: If the donor asks the collector to provide identification, the collector must show the donor some form of identification. It must include the collector's name and the employer's name, address, and telephone number. It does not have to be picture identification or include a home address and telephone number.

(4) The collector reviews the instructions on the back of the CCF with the donor.

(5) The collector begins entering information and/or ensures that the required information is provided at the top of the CCF (the laboratory name and address and a pre-printed specimen ID number) and in Step 1 of the CCF (employer's name, address, and I.D. number, if applicable, MRO name, address, phone and fax number, donor SSN or employee ID number, reason for test, drug test to be performed, and collection site information).

Note: A specific MRO's name and address must appear on the form rather than the name of the clinic or medical facility.

(6) The collector asks the donor to remove any unnecessary outer clothing (e.g., coat, jacket, hat, etc.) and to leave any briefcase, purse, or other personal belongings he or she is carrying with the outer clothing. The donor may retain his or her wallet.

Note: The donor must not be asked to remove other articles of clothing, such as shirts, pants, dresses, or under garments. Additionally, the donor must not be requested or required to remove

all clothing and wear a hospital or examination gown.

(7) The collector directs the donor to empty his or her pockets and display the items to ensure that no items are present that could be used to adulterate the specimen. If nothing is there that can be used to adulterate a specimen, the donor places the items back into the pockets and the collection procedure continues.

Note: If an item is found that appears to have been brought to the collection site with the intent to adulterate the specimen, a direct observed collection procedure is used. If the item appears to be inadvertently brought to the collection site, secure the item and continue with the normal collection procedure.

(8) The collector instructs the donor to wash and dry his or her hands, preferably under the collector's observation, and must not wash his or her hands again until after delivering the specimen to the collector.

Note: The donor must not be allowed any further access to water or other materials that could be used to adulterate/dilute the specimen.

(9) The collector either gives the donor or allows the donor to select the collection container from the available supply. Either the collector or the donor, with both present, then unwraps or breaks the seal of the collection container.

Note: Do not unwrap or break the seal on any specimen bottle at this time.

Note: Do not allow the donor to take anything except the collection container into the room used for urination.

(10) The collector directs the donor to go into the room used for urination, provide a specimen of at least 45 mL (split specimen collection) or 30 mL (single specimen collection), not to flush the toilet, and return with the specimen as soon as possible after completing the void.

Note: The donor is always permitted to provide a specimen in private unless a direct observed collection has been authorized.

Note: Pay close attention to the donor during the entire collection process to note any conduct that clearly indicates an attempt to substitute or adulterate a specimen. If you detect such conduct, immediately begin a new direct observed collection using a second CCF. Provide an appropriate comment on the "Remarks" line in Step 2 on the first CCF and submit it along with the specimen to the laboratory for testing. This will ensure that the laboratory knows that two separate specimens are being submitted for testing; the first one possibly being adulterated or substituted. Additionally, inform a supervisor that a collection took place under direct observation and the reason for doing so.

(11) After the donor hands the specimen to the collector, the collector must measure the temperature of the specimen, check the specimen volume, and inspect the specimen for

adulteration or substitution.

(a) Temperature. Check the temperature of the specimen within four minutes after the donor hands you the specimen. The acceptable temperature range is 32E-38EC/ 90E-100EF. Temperature is determined by reading the temperature strip originally affixed to or placed on the outside of the collection container after the donor hands you the specimen.

(i) If the temperature is within the acceptable range, the "Yes" box is marked in Step 2 on the CCF and the collector proceeds with the collection procedure.

(ii) If the temperature is outside the acceptable range, the "No" box is marked in Step 2 on the CCF and the collector immediately begins a direct observed collection procedure using a second CCF. The original specimen is sealed and sent with the first CCF to the laboratory with an appropriate comment on the "Remarks" line to indicate that a direct observed specimen was also being collected and submitted to the laboratory.

(b) Specimen Volume. Check to make sure that the specimen contains a sufficient amount of urine (i.e., 30 mL for a single specimen collection, 45 mL for a split specimen collection).

(i) Single specimen collection. If the volume is less than 30 mL, the action taken will depend on whether the temperature of the specimen is in or outside the acceptable range.

(1) If the temperature is in the acceptable range, the specimen is discarded and a second specimen is collected. The collector may use the same CCF for the second specimen, but must use a new specimen collection container. If the donor fails for any reason to provide 30 mL of urine for the second specimen collected, the collector will contact the agency to obtain guidance on the action to be taken.

(2) If the temperature is outside the acceptable range, a second specimen is collected under direct observation and both specimens are sent to the laboratory for testing. The collector must use a separate CCF for each specimen and provide an appropriate comment on each CCF to indicate why two specimens were collected. If the donor fails for any reason to provide 30 mL of urine for the second specimen collected, the collector contact the agency to obtain guidance on the action to be taken.

Note: In either case, when a second specimen is to be collected, you may give the donor a reasonable amount of fluid to drink to provide a second specimen distributed reasonably through a period of up to 3 hours, or until the donor has provided a new sufficient amount of urine, whichever occurs first.

(ii) Split specimen collection. If the volume is less than 30 mL, the action taken will depend on whether the temperature of the specimen is in or outside the acceptable temperature range.

(1) If the temperature is in the acceptable range, the specimen is discarded and a second specimen is collected. The collector may use the original CCF for the second specimen, but should use a new specimen collection container. If the donor fails to provide 45 mL for the second specimen collected, the donor forfeits the right to the use of a split specimen collection procedure and the collector submits the second specimen as a single specimen collection with an appropriate comment on the "Remarks" line on the CCF.

(2) If the temperature is outside the acceptable range, a second specimen is collected under direct observation and both specimens are sent to the laboratory for testing. The collector must use a separate CCF for each specimen and provide an appropriate comment on each CCF to indicate why two specimens were collected. If the donor fails to provide 45 mL for the second specimen collected, the donor forfeits the right to the use of a split specimen collection procedure and the collector submits the second specimen as a single specimen collection (regardless of the volume collected) with an appropriate comment on the "Remarks" line on the CCF.

Note: In either case when a second specimen is to be collected, you may give the donor a reasonable amount of fluid to drink to provide a second specimen distributed reasonably through a period of up to 3 hours, or until the donor has provided a new sufficient amount of urine, whichever occurs first.

(iii) Split specimen collection. If the volume is between 30 and 45 mL, the action taken will depend on whether the temperature of the specimen is in or outside the acceptable temperature range.

(1) If the temperature is in the acceptable range, all of the urine should be poured into one specimen bottle (Bottle A). Bottle A is sent to the laboratory along with the CCF. The collector should provide an appropriate comment on the "Remarks" line on the CCF that the donor did not provide a sufficient volume of urine for the split (Bottle B) specimen. The donor forfeits the use of a split specimen collection procedure.

(2) If the temperature is outside the acceptable range, a second specimen is collected under direct observation and both specimens are sent to the laboratory for testing. The collector must use a separate CCF for each specimen and provide an appropriate comment on each CCF to indicate why two specimens were collected.

(3) If the donor fails to provide 45 mL for the second collection, the second specimen is submitted as a single specimen collection and the collector should provide an appropriate comment on the "Remarks" line on the CCF that the donor did not provide a sufficient volume of urine for the split (Bottle B) specimen. The donor forfeits the use of a split specimen collection procedure.

Note: You may give the donor a reasonable amount of fluid to drink to provide a second specimen distributed reasonably through a period of up to 3 hours, or until the donor has provided a new sufficient amount of urine, whichever occurs first.

(c) Adulteration or Substitution. Inspect the specimen for unusual color, presence of foreign objects or material, or other signs of adulteration (e.g., if you notice any unusual odor). If it is apparent from this inspection that the donor has adulterated or substituted the specimen (e.g., the specimen is blue, exhibits excessive foaming when shaken, or has a smell of bleach), a second collection using direct observation procedures is conducted. The first specimen and the specimen collected using direct observation are both sent to the laboratory for testing. The first specimen is always sent to the laboratory even though it may have had an insufficient volume for either a single or split specimen collection. If the donor does not provide the required amount of urine for the second collection using direct observation, the collector submits the second specimen as a single specimen collection (regardless of the volume) and provides appropriate comments on the "Remarks" line on both CCFs.

Note: When a second specimen is to be collected, you may give the donor a reasonable amount of fluid to drink to provide a second specimen distributed reasonably through a period of up to 3 hours, or until the donor has provided a new sufficient amount of urine, whichever occurs first.

Note: Under no circumstance is the collector permitted to collect and add or combine urine from two separate voids.

(12) The sealed specimen bottle is then unwrapped or opened in the donor's presence after the donor gives the specimen in the collection container to the collector. The collector or the donor may unwrap or open the specimen bottle.

Note: There will be two specimen bottles to be unwrapped or opened if a split specimen was collected.

Note: Both the collector and donor will maintain visual contact of the specimen until the label/seal is placed over the specimen bottle cap/lid. The donor will never drop off any specimen and just leave the area. The donor will not leave the collection area until he/she visually initials the bottle, signs all required documents, sees their specimen placed in the leak proof collection bag with copy 1 of the CCF, the bag is sealed, signed, and dated and placed in the shipment box. After all of the above is completed, only then is the donor allowed to leave the collection area.

(13) The collector pours the specimen from the collection container into a specimen bottle, places the lid/cap on the bottle, and uses the "A" bottle tamper-evident label / seal. The "B" bottle label is discarded. If a split specimen collection procedure is used, the collector pours 30 mL of urine into a specimen bottle, places the lid/cap on the bottle and uses the "A" bottle label/seal. The collector then pours the remaining urine (at least 15 mL) into a second bottle, places the lid/cap on the bottle, and uses the "B" bottle label/seal.

Note: The tamper-evident label/seal must be placed over the lid/cap to ensure that the lid/cap cannot be removed without destroying the label/seal. The donor must be present to observe the sealing of the specimen bottle(s). If the donor leaves the area without initialing the bottle seal, the specimen will be dumped and the donor will be recalled to provide another sample.

(14) The collector writes the date on the tamper-evident label(s)/seal(s). The donor is

required to initial the tamper-evident label(s)/seal(s).

Note: Occasionally, the tamper-evident label/seal provided with the CCF will not properly adhere to the specimen bottle because of environmental conditions (e.g., moisture, temperature, specimen bottle material). When this occurs, the collector should still apply the tamper-evident label/seal provided with the CCF and then apply a second, separate tamper-evident seal to seal the specimen bottle. This second seal should be placed perpendicular to the CCF label/seal to avoid obscuring information on the CCF label/seal. This second seal must be initialed and dated by the collector and should be initialed by the donor (i.e., if the donor is still present when it is apparent that the CCF label/seal is not properly adhering to the specimen bottle; however, a label/seal may appear to adhere when initially placed on the bottle, but after several minutes the label/seal begins to lift off along the edges). The collector must also provide an appropriate comment on the "Remarks" line (CCF, Step 2) stating why the second seal was used.

Note: If while sealing and initialing the CCF label/seal the collector or donor accidentally breaks/damages the seal, the collector must apply a second, separate tamper-evident seal to seal the specimen bottle. This second seal should be placed perpendicular to the CCF label/seal to avoid obscuring information on the CCF label/seal. This second seal must be initialed and dated by the collector and initialed by the donor. The collector must also provide an appropriate comment on the "Remarks" line (CCF, Step 2) stating why the second seal was used.

Note: Since the specimen bottle is now sealed with tamper-evident tape, Copy 1 ofthe CCF is completed and placed in the leak proof bag, the bag is sealed, signed, and dated, and the donor is allowed to wash his or her hands if he or she desires to do so. The door to the latrine will be left open for donor's specimen bottle observation while performing hand washing or the donor may use an antibacterial hand wipe which will be provided at the collector's desk.

(15) The donor reads the certification statement on Copy 2 of the CCF (Step 5), signs and dates the certification statement, provides date of birth, printed name, and day and evening contact phone numbers.

Note: If the donor refuses to sign the form, the collector must make a notation on the "Remarks" line to that effect. Otherwise, without the collector's comment, a CCF without the donor's signature could result in a canceled test. The same procedure should be followed if the donor refuses to initial the label(s).

(16) The collector completes the chain of custody on the CCF (Step 4) by printing his or her name, signing where indicated, recording the date and time of the collection, and indicating the specific name of the delivery service to which the specimen bottle(s) are being released.

(17) The collector removes Copy 5 from the CCF and gives it to the donor. The donor may now leave the collection site.

Note: At this time, the collector can tell the donor to list any prescription and over-the-counter medications he or she may have recently taken on the back of the donor copy (Copy 5) of the CCF, but not on any other copy. This information will help the donor remember what

medications he or she may have taken if a positive result is reported by the laboratory to the MRO.

(18) The collector places the specimen bottle(s) and Copy 1 of the CCF inside the appropriate pouches of the leak-resistant plastic bag, seals the pouches, and initials and dates the seal.

(19) The donor is now free to leave the area.

(20) T he collector places the sealed plastic bag in an appropriate shipping container (e.g., express carrier mailer) and seals the shipping container as appropriate.

Note: If a collector is collecting several specimens within a short period of time, the sealed plastic bags may be placed into a single shipping container. The collector must maintain visual contact of the sealed plastic bags until all plastic bags are sealed in the single shipping container.

Note: The collector must ensure that each specimen is shipped to a laboratory as expeditiously as possible, the same day preferably. If the specimens are not ready for shipment the same day the specimens will be logged and placed in temporary storage room.

(21) The collector sends Copy 2 to the MRO and Copy 4 to the employer. Copy 3 is retained by the collector.

The collection procedure is now complete.

b. Shy Bladder Procedure:

(1) When a donor is unable to provide a urine specimen, the donor may have intentionally urinated prior to arriving at the collection site, could not provide a specimen as directed by the collector, has a physical disability making it impossible to provide a specimen, or has a "shy bladder." The term "shy bladder" usually refers to an individual who is unable to provide a specimen either upon demand or when someone is nearby during the attempted urination.

(2) If a donor tells the collector, upon arrival at the collection site, that he or she cannot provide a specimen, the collector must begin the collection procedure regardless of the reason given.

(3) At the point in the collection procedure where the collector and donor unwrap or open a collection container, the collector does the following:

(a) Requests the donor to try to provide a specimen.

Note: The donor demonstrates his or her inability to provide a valid specimen when the donor comes out of the enclosed toilet stall with an empty collection container.

(b) Directs the donor to drink some fluids.

Note: The donor is given a reasonable amount of fluid to drink distributed reasonably through a period of up to 3 hours, or until the donor has provided a new sufficient amount of urine, whichever occurs first.

Note: The donor must remain under the direct observation of the collector or an agency representative to prevent the donor from possibly compromising the collection process.

Note: If the donor refuses to drink fluids as directed or refuses to attempt to provide a urine specimen, the collection procedure is discontinued and a "refusal to test" is noted on the "Remarks" line of the CCF.

(c) Instructs the donor to let you know when he or she is able to provide a sufficient quantity of specimen. The collector uses the CCF from the first attempt.

Note: It is recommended that the collector allow sufficient time to have only one additional attempt rather than having to document several unsuccessful attempts.

(d) Maintains a record of the time of each attempt, whether there was no specimen provided or the quantity of specimen provided, and the total ounces of fluid given to the donor.

(e) Discards any inadequate specimen and the collection container that was used for the void, but retains the CCF.
Note: If there was actually no specimen provided on an attempt, the collection container may be used for the next attempt.

(f) Discontinues the collection procedure and notifies the agency of a potential "shy bladder" situation if after a period of three hours (i.e., from the time the donor first demonstrated that he or she was unable to provide a sufficient quantity of specimen) the donor is still unable to provide an adequate specimen.

(g) Indicates "Shy Bladder" on the "Remarks" line of the CCF and attaches a copy of the record documenting the attempts to collect a specimen. Copy 1 is discarded since no valid specimen was collected and the other copies of the CCF are distributed as appropriate.

c. Direct Observed Collection:

(1) A direct observed collection procedure is the same as a routine collection procedure with the additional requirement that an observer physically watches the donor urinate into the collection container.

(2) The use of an observer may occur only when:

(a) A previous drug test was reported either positive for a drug, dilute, adulterated,

substituted, unsuitable for testing, or canceled because the split specimen was not tested;

(b) The drug test is a return-to-duty or a follow-up test;

(c) The agency/employer believes that the donor may alter or substitute the specimen to be provided; or

(d) During a routine collection, the temperature of the specimen collected is outside the acceptable range, the collector observed materials brought to the collection site or donor conduct indicated a possible attempt to adulterate or substitute a specimen, or the collector believes that the specimen has been adulterated (e.g., the specimen is blue, exhibits excessive foaming when shaken, has smell of bleach, etc.).

Note: The observer must be the same gender as the donor even if the observer has a medical background/training. The collector may serve as the observer when the collector is the same gender as the donor. If not, the collector must call upon another individual (who is the same gender as the donor) to act as the observer.

Note: With regard to chain of custody, the observer must never touch/handle the collection container.

(3) After the donor has completed urinating into the collection container, the donor and observer leaves the enclosed toilet stall/restroom and the donor hands the collection container directly to the collector.

Note: The observer must maintain visual contact of the collection container until the donor hands the container to the collector.

Note: If the observer and collector are one and the same, the collector may receive the collection container from the donor while they are both in the enclosed toilet stall/restroom. The collector continues with the collection procedure, checks the box for an observed collection in Step 2 on the CCF, and provides the name of the observer and the reason for an observed collection on the "Remarks" line in Step 2 on the CCF. A separate sheet explaining the use of an observed collection may be attached to the CCF if there is insufficient room on the "Remarks" line.

11. INSTRUCTIONS FOR COMPLETING THE FEDERAL DRUG TESTING CUSTODY AND CONTROL FORM.

a. All urine specimens must be collected using chain of custody. Chain of custody is the term used to describe the process of documenting the handling and storage of a specimen from the time a donor gives the specimen to the collector to the final disposition of the specimen. For specimens collected under the Mandatory Guidelines, the Office of Management and Budget (OMB) approved Federal Drug Testing Custody and Control Form (CCF) must be used to document the collection of a specimen at the collection site. The CCF is available from a number of different sources (e.g. laboratories, collectors, MROs) although it is usually provided by the laboratory.

b. A sample of the CCF (OMB No. 0930-0158, Exp. Date: 6/30/2003) is on the SAMHSA web site (www.health.org/workpl.htm). All discussions throughout this revised SOP refer to this version of the CCF form.

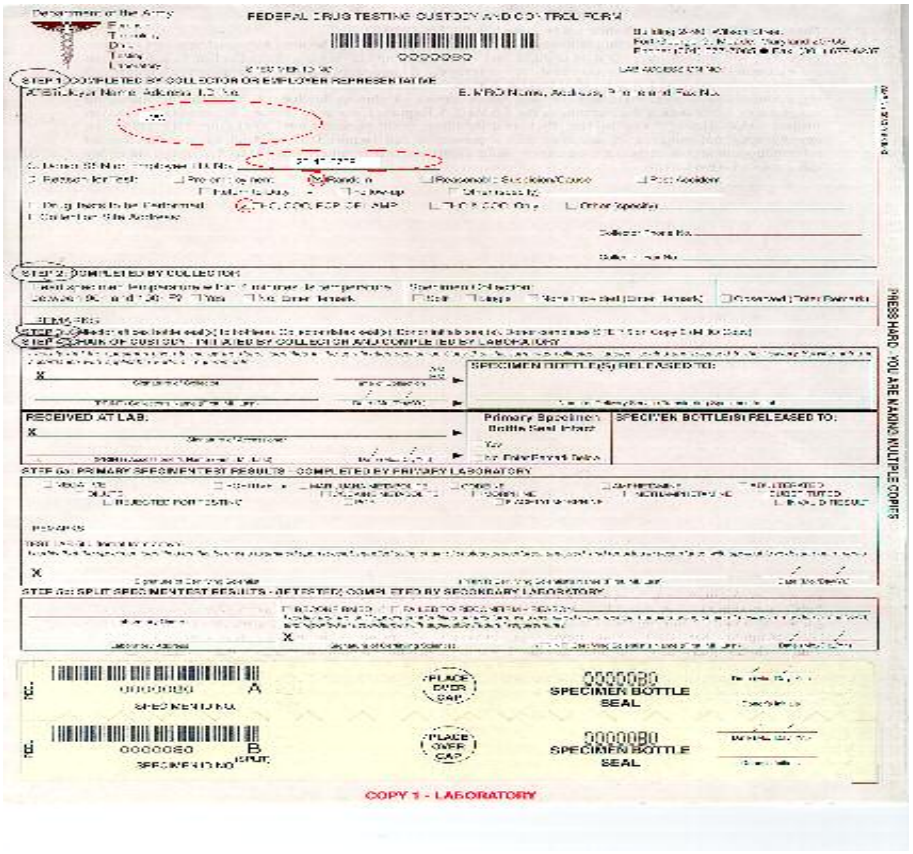
c. The CCF consists of the following five copies:

Copy 1. Laboratory Copy
Copy 2. Medical Review Officer Copy
Copy 3. Collector Copy
Copy 4. Employer Copy
Copy 5. Donor Copy

Copy 1 accompanies the specimen to the testing laboratory, Copy 2 is sent to the MRO, Copy 3 is retained by the collector, Copy 4 is sent to the employer, and Copy 5 is given to the donor.

d. The CCF is completed as follows:

Step 1. This step is completed by the collector or employer representative. The employer name and address and the MRO name and address may be preprinted or handwritten. The collector will normally enter the donor's social security number after verifying the donor's identity. The collector also marks the appropriate box to indicate the reason for the test and the appropriate box for the drug tests to be performed. The collector then enters the information required for the collection site.



Department of the Army

FEDERAL DRUG TESTING CUSTODY AND CONTROL FORM

STEP 1 COMPLETED BY COLLECTOR OR EMPLOYER REPRESENTATIVE

STEP 2 COMPLETED BY COLLECTOR

STEP 3 PAIR OF SPECIMEN BOTTLES INITIALED BY COLLECTOR AND SIGNED BY LABORATORY

SPECIMEN BOTTLE(S) RELEASED TO:

RECEIVED AT LAB:

Primary Specimen Bottle Seal Intact

SPECIMEN BOTTLE(S) RELEASED TO:

STEP 4a: PRIMARY SPECIMEN TEST RESULTS - COMPLETED BY PRIMARY LABORATORY

STEP 4b: SPLIT SPECIMEN TEST RESULTS - (IF TESTED) COMPLETED BY SECONDARY LABORATORY

TO: A SPECIMEN NO.

PLACE OVER SEAL

SPECIMEN BOTTLE SEAL

TO: B SPECIMEN NO.

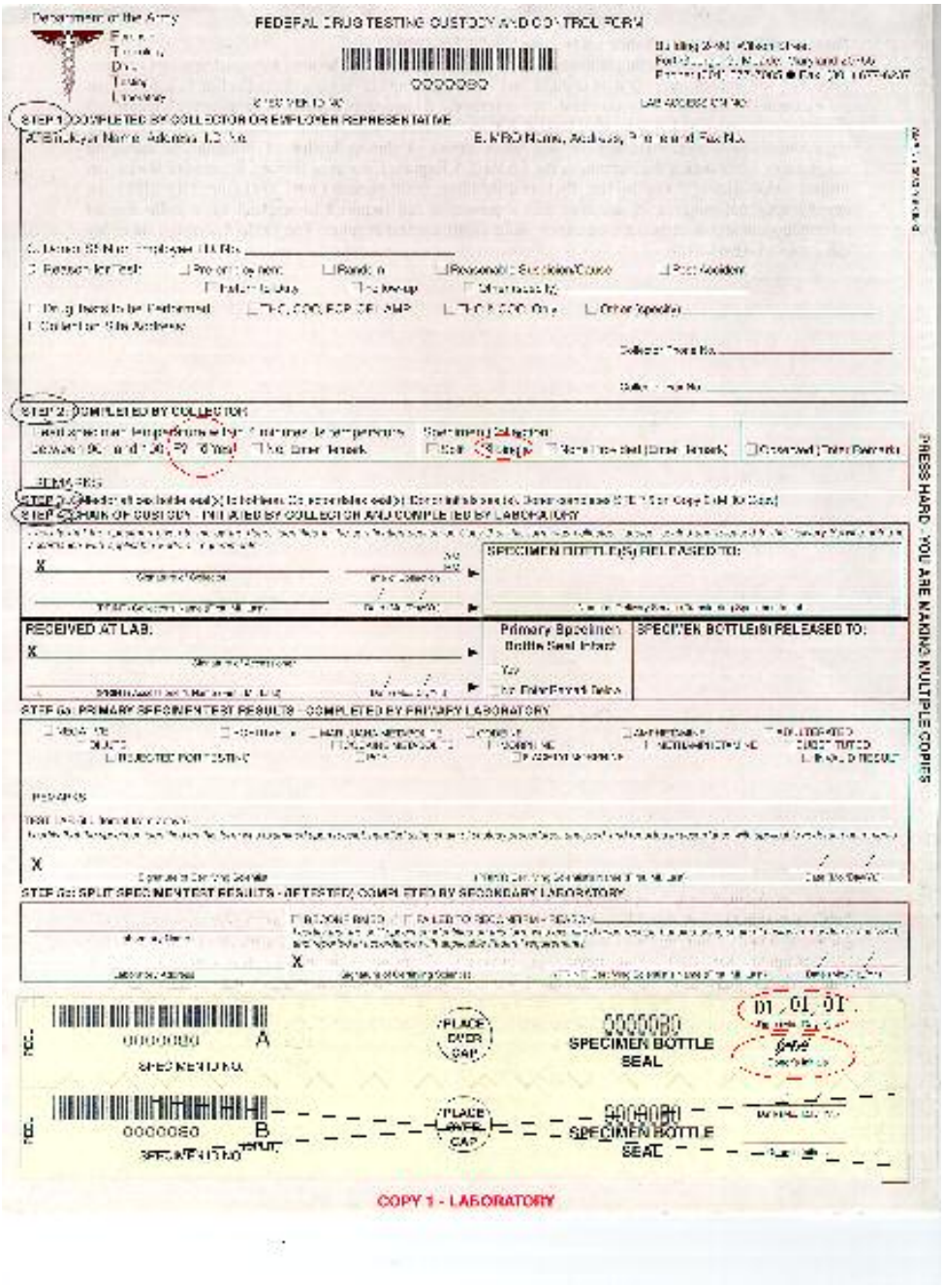
PLACE OVER SEAL

SPECIMEN BOTTLE SEAL

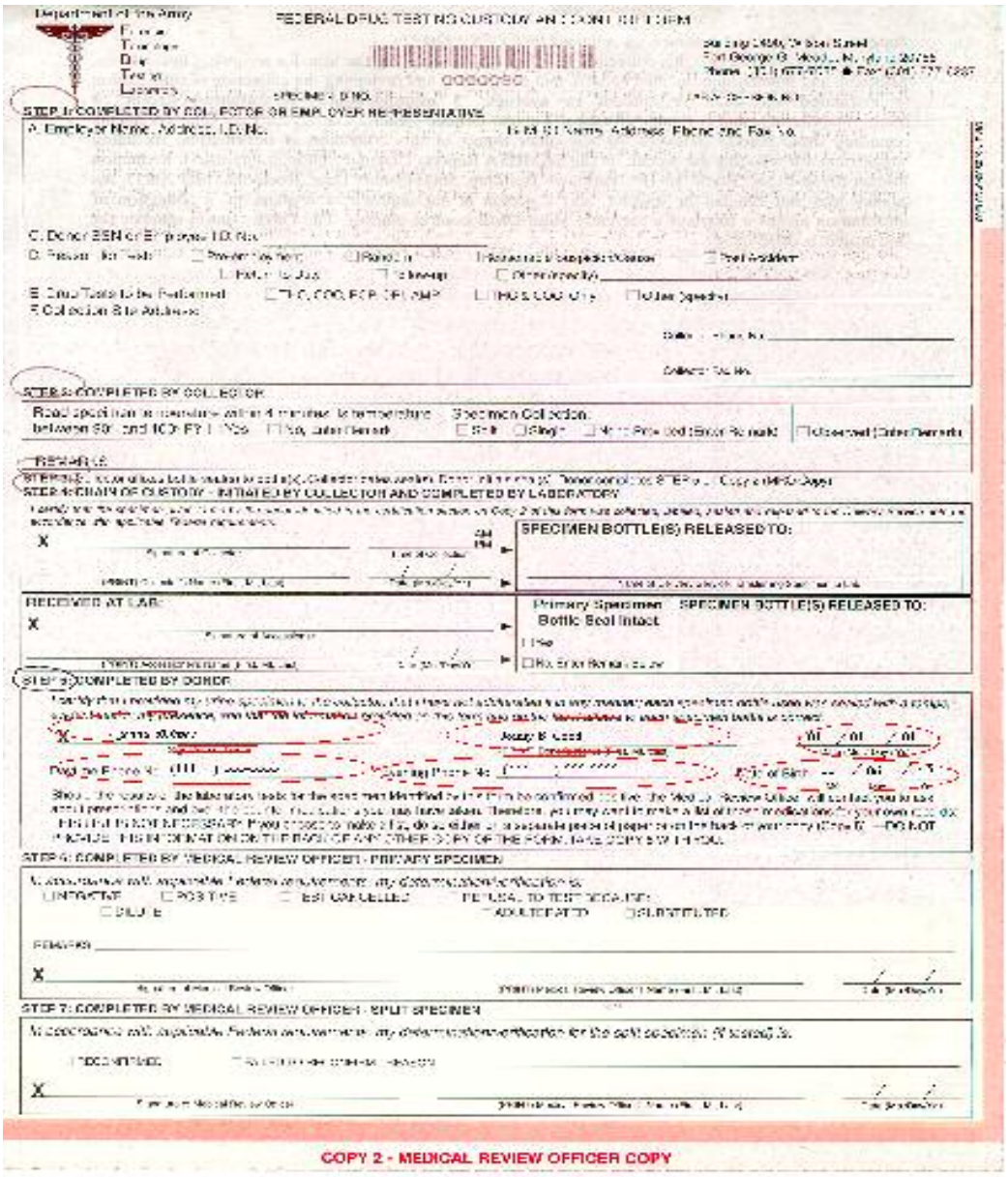
PRESS HARD. YOU ARE MAKING MULTIPLE COPIES

COPY 1 - LABORATORY

Step 2. This step is completed by the collector after receiving the specimen from the donor and measuring the temperature of the specimen. This step requires the collector to mark the appropriate box to indicate if the temperature of the specimen was within the required temperature range; but also requires the collector to indicate whether it is a split specimen or single specimen collection, to indicate if no specimen was collected and why, or to indicate if it was an observed collection and why.

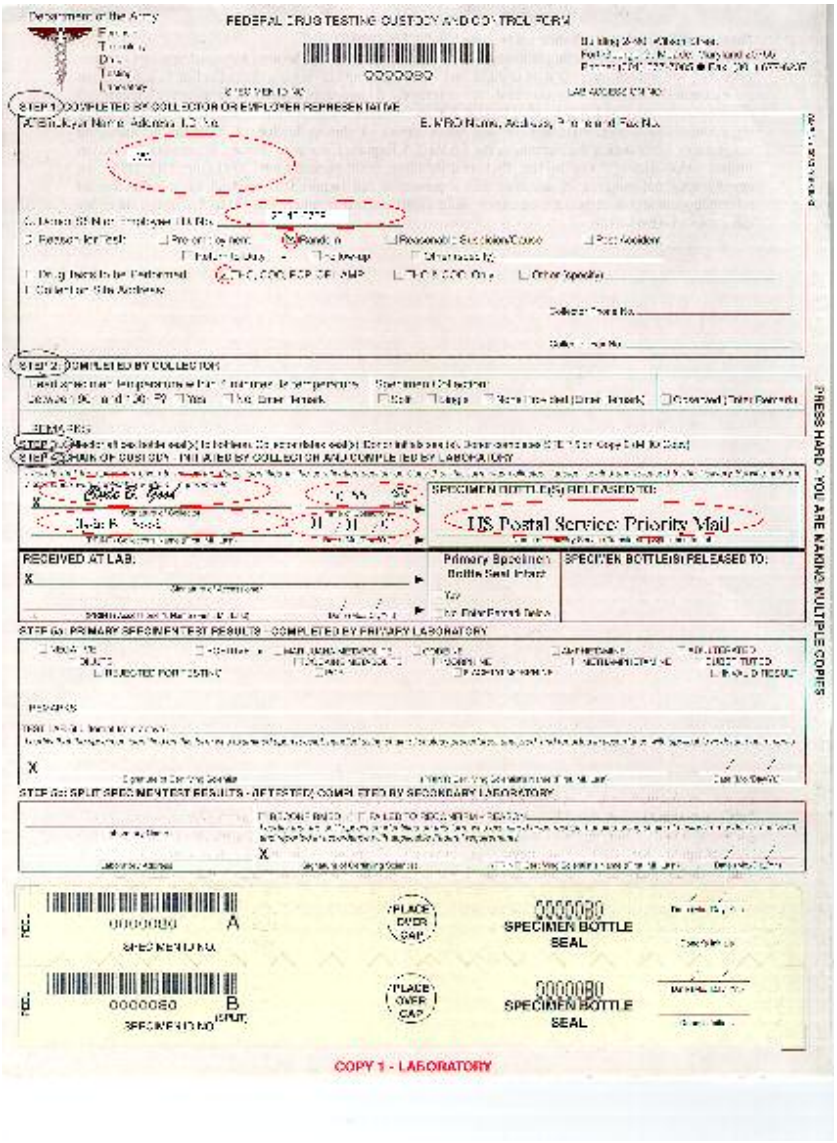


Step 3. This step instructs the collector to seal the specimen bottle(s), have the donor initial the bottle seal(s) (SEE figure on step 2), and then instruct the donor to complete step 5 on the MRO copy (Copy 2) below.



Step 4. This step is initiated by the collector and then completed by the laboratory after the specimen is accessioned by the laboratory. This step requires the collector to only sign the form

once to certify that the specimen was collected, labeled, sealed, and released for shipment to the laboratory in accordance with Federal requirements. The collector is also required to note the time of the collection, the date of collection, and the specific name of the delivery service to which the specimen is released for shipment to he laboratory.



Note: There is no requirement for couriers, express carriers, or postal service personnel to document chain of custody for the specimens during transit because they do not have access to the specimen(s) or the CCF. Chain of custody annotations resume when the shipping container/package is opened and an individual at the laboratory has access to the specimen bottle(s) and the CCF. At the laboratory, the accessioned is required to document the condition of the primary specimen bottle seal, sign the CCF, print his/her name, record the date the specimen was accessioned, and indicate to whom the specimen was released. The entry for the "Specimen Bottle(s) Released To" may include transfer to temporary storage or transfer to another individual. After this transfer, chain of custody of the specimen bottle(s) is documented by the laboratory on an internal chain of custody form.

Step 5(a). This step is completed by the laboratory to document the test results on the primary specimen.

Step 5(b). This step is completed by the laboratory to report the split specimen result if the split specimen is tested.

The bottom area of copy 1 is reserved for the tamper-evident specimen bottle seal(s)/label(s). There must be two labels (i.e., one marked with the letter "A" to designate the primary specimen and the other marked with the letter "B" to designate the split specimen) to accommodate collecting split specimens and each must have the same preprinted specimen identification number that appears at the top of the CCF. Each label must also have a place for the collector to annotate the date of the collection and a place for the donor to initial each label after it is placed on the specimen bottle. If a single specimen collection procedure is used, the second label (i.e., the "B" label) is discarded by the collector.

12. PACKING AND SHIPPING REQUIREMENTS.

a. The designated person responsible for shipping civilian specimens to the laboratory (normally the IBTC or a certified collector) will:

(1) Place the specimen bottle and Copy 1 of the CCF into a leak proof bag. The leak proof bag should be sealed to prevent access to the specimen bottle and copies of the CCF; (Example: If a zip lock type bag is used, tape over the opening to prevent access to the specimen.)

(2) Place the leak proof package into a shipping container;

NOTE: One or more leak proof containers may be placed into one shipping container if multiple specimens are to be shipped to the supporting laboratory. The collector may complete each CCF to indicate that the specimen has been released to a specific carrier then place each specimen bottle along with its Cpy 1 of the CCF in a leak proof bag provided the collector maintains visual contact of each plastic bag until all plastic bags are sealed in the single shipping container.

(3) Place absorbent pouch in shipping box;

(4) Close the box and tape along the center seam all the way around the box and then cover all sides, edges and flaps with tape;

(5) Sign payroll signature across the seal on the top and bottom of the box; and

(6) Place contents in an approved shipping container for the carrier shipping the specimen(s) to the laboratory.

NOTE: The U.S. Postal Service and other couriers require the use of a secondary barrier that is leak proof (such as a plastic bag) when shipping potentially hazardous biological materials.

13. HAZARDOUS WASTE.

a. According to Safety Division, Environmental Branch, Directorate of Environment and Safety (DES), the ASAP is not required to have a hazardous waste team. The local medical treatment facility (MTF) will assume the responsibility for the ASAP hazardous waste team.

b. The bio-safety goal is accomplished through the successful identification and removal of hazardous conditions by:

(1) Providing hazardous waste training. It is recommended that all personnel working in the IBCP attend this training. Contact Safety Branch, 239-2245 to arrange for a class.

(2) Hepatitis B inoculations are available and encouraged for all personnel working in the IBCP as well as for members of the Civilian Specimen Collection Team (CSCT). The MTF's Occupational Health Office will administer this program.

(3) No eating, drinking, chewing, or smoking will be done in the IBCP. Glove protection will be worn at all times while handling full or half-empty urine.

(4) No consumable or disposable equipment will be used more than once. Discard all urine samples down the toilet and not the sink. All sample bottles will be rendered non-usable by cutting, puncturing, crushing or burning. All potentially infectious waste will be deposited in a trash container that is double-lined with heavy, yellow trash bags. These trash containers will be covered when not in use. The large trash bags will only contain empty sample bottles or used consumables and not weigh over 25 lb. When they are full or ready to be disposed of, they will be tied off at the top with a triple layer of green tape. They will then are placed into a large brown trash bag and be taped shut at the top with green tape. The trash bags will be deposited in the nearest disposable trash bin for removal. Trashcans that contain used sample bottles or used consumables will be emptied every day in the appropriate manner. Trashcans will be cleaned with a disinfectant after being emptied.

(5) Every surface that comes in contact with urine, used urine bottles, or used consumables will be cleaned immediately after use with a disinfectant.

(6) Refrigerators will be cleaned at a minimum of once a month with a disinfectant.

(7) Urine spills will be cleaned up with an absorbent pad, and then paper towels and a disinfectant.

14. SECURITY.

a. AR 195-5 covers the security for evidence storage.

b. Key control is handled IAW AR 195-5, Chapter 4, and Paragraph 4-5.

c. Internal key control for the IBCP is established by the Physical Security Officer and Key Custodian.

15. SAFETY.

a. Rubber gloves will be worn at all times while working with specimen samples.

b. Materials for clean up of specimen spillage will be present before working with the urine specimens.

c. All work surfaces where specimen work is conducted will be cleaned with disinfectant immediately after the work is completed. When using spraying disinfecting agents, gloves and eye protection will be worn.

d. A first aid kit will be present at all times in the IBCP.

e. A fire extinguisher will be present at all times in the IBCP. The fire extinguisher will be an approved ABC type extinguisher and will be checked at a minimum of once a month.

f. A listing of emergency phone numbers for evacuation, fire, bomb threats, poison control, military police and the local MTF will be posted in a conspicuous place for all to use if necessary.

NOTE: Random Urinalysis Testing of Healthcare Providers will be conducted at Irwin Army Hospital, Bldg 602, Fort Riley, KS. Commander, USA MEDDAC, will select CPs (Collection Providers) and these providers will be trained and certified by the Installation Biochemical Testing Coordinator on a yearly basis. All TDP urine samples collected at Irwin Army Hospital will be IAW all regulations governing Urinalysis Testing. Samples will be turned in to the IBTP for quality assurance prior to shipment of samples to the Forensic Drug Testing Laboratory.

16. The POC for this SOP is the undersigned at 239-1829.

WILLIAM E. POWERS
Chief, Soldier and Family Support Center